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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,254

07/11/2003

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08/20/2008

EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

08/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,254	THIERRY-PALMER ET AL.	
	Examiner	Art Unit	
	Leon B. Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/26/08 has been entered.

Pages 2 & 7 of the specification should be replaced as the current copies are not properly aligned on the page.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

From the IDS of 6/20/2007, applicant writes:

The application before the U.S. Patent Office describes and claims a kit for measuring loss of vitamin D binding proteins into urine by assaying for the ability of a sample of urine to bind labeled 25-hydroxyvitamin D₃. The loss of vitamin D binding proteins into urine is an indicator of salt-sensitivity.

The claims do not set forth the invention as recited in the above statement. Applicant's invention would appear to necessarily include the correlation with salt sensitivity and that is now lacking from claim 6. Applicant's claims do not seem to define an invention which results in an evaluation of salt sensitivity of a patient. Applicant needs to make it clear what is being measured from the sample and exactly how it's being measured and then how that correlates to salt sensitivity in order to distinctly claim the subject matter which applicant regards as the invention.

Further, it is unclear what is being claimed as if the invention is designed to be a simple test of the presence of proteins that bind 25-OHD, it is unclear why the samples are split and the excess unlabeled substrate needs to be added.

Applicant's nomenclature is confusing. Applicant sometimes uses the designation "vitamin D" and sometimes "vitamin D₃" seemingly interchangeably and it is unclear what is desired.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 9 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al(4269777) and Norman et al(3772150) in view of Garman (6054282), Blume(6010861) and Cook(5989854).

DeLuca and Norman both teach radiolabeled 25-OHD to be used in assays. The label is made from non-labeled 25-OHD therefore it would have been obvious at the time the invention was made to make a kit comprising the radiolabeled compound and unlabeled compound for use in the methods of DeLuca and Norman as a reagent and control.

“When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either *in the same field or a different one(emphasis added)*. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR v Teleflex* (500 US ____ 2007) pages 12-13 of the decision.

It is well known in the art to use both radiolabelled and unlabelled reagents in an assay for reasons including but not limited to controlling the signal produced to be detected. Many examples exist in the art showing assays using both radiolabelled and unlabelled versions of the same reagents in binding assays, e.g. Garman (see e.g. Fig 1), Blume (col 67) and Cook (Col 5-7) and thus it would have been obvious to one of ordinary skill in the art to combine radiolabelled and unlabelled 25-OHD in a kit.

Applicant is further directed to the same pages 12-13 of *KSR* “ ... the Court has held that a “patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”

It would have been obvious at the time the invention was made to include instructions with a kit comprising the radio labeled compound because at the time the invention was made it would have been notoriously old and well known to include instructions for use in any kit intended to have a practical use. The subject matter of those instructions does not serve to distinguish the invention from the prior art because the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. see In re Gulack, 703 F.2d 1381 (Fed. Cir. 1983) & In re Ngai, 70 USPQ2d 1862 (CA FC 2004) .

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Leon B Lankford/
Primary Examiner, Art Unit 1651